UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01- 12257-PBS** **Subcategory Case. No. 06-11337**
THIS DOCUMENT RELATES TO: *United States of America ex rel. Ven-A-Care of the Florida Keys, Inc., et al. v. Dey, Inc., et al.*, Civil Action No. 05-11084-PBS	**Hon. Patti B. Saris** **Magistrate Judge Marianne B. Bowler**

DEFENDANTS DEY, INC., DEY, L.P., AND DEY L.P., INC.'S MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS THE RELATOR'S COMPLAINTS FOR LACK OF SUBJECT MATTER JURISDICTION

Dated: June 29, 2009

Paul F. Doyle (BBO # 133460)
Sarah L. Reid (*pro hac vice*)
William A. Escobar (*pro hac vice*)
Neil Merkl (*pro hac vice*)
KELLEY DRYE & WARREN LLP
101 Park Avenue
New York, New York 10178
Telephone: (212) 808-7800
Facsimile: (212) 808-7897
Attorneys for Defendants
Dey, Inc., Dey L.P., Inc. and Dey, L.P.

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PRELIMINARY STATEMENT

Defendants Dey, Inc., Dey L.P., Inc. and Dey, L.P. (collectively, "Dey") respectfully move this Court to dismiss Relator Ven-A-Care of the Florida Keys, Inc. ("Ven-A-Care") and its *qui tam* complaints because the Court lacks subject-matter jurisdiction pursuant to the public disclosure/original source rule of 31 U.S.C. § 3730(e)(4) of the False Claims Act ("FCA"). The allegations in Ven-A-Care's *qui tam* complaints are "based upon" publicly disclosed reports prepared by agencies and departments of the United States Government (the "Government"), news media, and Government audits and investigations. Ven-A-Care does not qualify as an "original source" of the allegations in its complaints because Ven-A-Care did not have "direct" and "independent" knowledge of the publicly disclosed information. Therefore, this Court does not have subject matter jurisdiction over Ven-A-Care's *qui tam* complaints.

PROCEDURAL HISTORY

This action originates from two separate *qui tam* actions filed by Ven-A-Care. The first action was filed in the U. S. District Court for the Southern District of Florida in 1995 (the "Florida Action"). Dey was added to the Florida Action on August 13, 1997, in the Second Amended Complaint ("Florida II Complaint").[1] Although the Florida II Complaint broadly alleges that a number of defendant drug manufacturers engaged in a scheme to defraud the Medicaid and Medicare programs, the only allegations of wrongdoing specific to Dey are that Dey caused "false" prices to be published in *Red Book* and *Blue Book*. *See* SJ Ex. 94, Florida II Compl. at ¶¶ 51, 71, 72, 88, 120, 121. The drugs alleged in the Florida II Complaint, which are also alleged in the United States' First Amended Complaint ("U.S. Compl." or "U.S.

[1] A copy of the Florida II Complaint is annexed as exhibit 94 to the June 26, 2009 Declaration of Sarah L. Reid in Support of Dey, Inc., Dey, L.P., and Dey L.P., Inc.'s Motion for Partial Summary Judgment, filed on June 26, 2009, Docket 6184. Exhibits previously filed to the Reid Declaration in support of Dey's Motion for Partial Summary Judgment will be referred to as "SJ Ex. __".

Complaint"), include albuterol sulfate inhalation solution 0.083% ("Albuterol UD") and cromolyn sodium ("Cromolyn"). *See id.*; SJ Ex. 13, U.S. Compl. at ¶ 25.

In December 1999, Ven-A-Care filed its Third Amended Complaint. *See* SJ Ex. 95. The Third Amended Complaint includes a reference to ipratropium bromide ("Ipratropium") in the general allegations section. See *id*. at pp. 141-42, 232-38. However, Ipratropium is not identified as a subject drug as to Dey. *See* SJ Ex. 95 at ¶¶ 205-206. Moreover, the Ipratropium chart does not list AWPs for Dey's Ipratropium or even indicate that the prices to Ven-A-Care are prices for Ipratropium sold or manufactured by Dey. Ven-A-Care added Dey's albuterol inhalation solution 0.5% ("Albuterol MD") in its Fourth Amended Complaint, filed December 2002. *See* Ex. 1, at p. 102.[2]

Ven-A-Care filed a second action against Dey and several other defendants in April 2000 ("Mass I. Complaint") in the District of Massachusetts ("Massachusetts Action"). *See* Ex. 2. The Mass. I Complaint makes allegations regarding Dey's albuterol inhalation aerosol metered-dose inhaler ("Albuterol MDI") and Albuterol MDI refill ("Albuterol Refill"). The complaint in the Massachusetts Action was amended three times. *See* Exhs. 3-5. The first complaint to name Ipratropium, as a subject drug for Dey was the Second Amended Complaint, filed in February 2002, in the Massachusetts Action. None of Ven-A-Care's *qui tam* complaints allege a specific Dey practice, policy, or instance of Dey "marketing the spread" for a drug at issue and based on information obtained by Ven-A-Care.[3]

In 2005, the claims against Dey in the Florida Action were severed and transferred to the

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[2] Ven-A-Care's Fourth Amended Complaint is annexed to the June 29, 2009 Declaration of Sarah L. Reid in Support of Dey's Motion to Dismiss the Relator's Complaints for Lack of Subject Matter Jurisdiction. Exhibits to the Reid Declaration in Support of Dey's Motion to Dismiss the Relator's Complaints for Lack of Subject Matter Jurisdiction will be referred to as "Ex. __."

[3] Ven-A-Care may claim that it made allegations regarding "marketing the spread" that are generally applicable to all defendants, but there is no allegation of any Dey-specific conduct.

District of Massachusetts. *See United States ex rel. Ven-A-Care of the Fla. Keys v. Dey, Inc.*, 498 F. Supp.2d 389, 393 (D. Mass. 2007). On August 24, 2006, the United States filed its complaint in intervention, which Ven-A-Care adopted as its complaint. *See* Ex. 6. The United States filed its First Amended Complaint on September 29, 2008. *See* Ex. 13.

The following drugs are alleged as subject drugs in the U.S. Complaint: Albuterol MDI, Albuterol Multi-Dose, Albuterol Refill, Albuterol UD, Cromolyn, and Ipratropium (the "Subject Drugs"). Unlike the *qui tam* complaints filed by Ven-A-Care, the U.S. Complaint also contains specific allegations that Dey "marketed the spread" to pharmacists to induce them to purchase Dey's products over the products of other manufacturers, makes allegations of Dey's policies and practices, and cites to documents obtained by the Government through subpoenas served during the seal period. *See* Ex. 13 at ¶¶ 53-54, 57.

ARGUMENT

Section 3730(e)(4) of the FCA provides:

> No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

In other words, 3730(e)(4) operates as a jurisdictional bar when: (1) there has been a "public disclosure," (2) the relator's suit is "based" on the disclosure, and (3) the relator was not the original source of the information on which its suit is based. *See Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 467 (2007); *In re Pharm. Indus. AWP Litig. (U.S. ex rel. West v. Ortho-McNeil Pharm., Inc.)*, 538 F. Supp. 2d 367, 375-79 (D. Mass. 2008) (hereinafter, "*West*"). "The Relator carries the burden of proving jurisdiction." *West*, 538 F. Supp. 2d at 375.

I. THERE HAVE BEEN NUMEROUS "PUBLIC DISCLOSURES"

The relevant allegations here are those in the Government's First Amended Complaint. *See Rockwell*, 549 U.S. at 473. In evaluating whether a public disclosure predates a particular allegation, courts look to the time when the allegation first appeared in a complaint, not the inception of the action. *See United States ex rel. Atkinson v. Pa. Shipbuilding Co.*, 255 F. Supp. 2d 351, 367 n.15 (E.D. Pa. 2002).

The core allegations in the U.S. Complaint – that published prices were significantly higher than providers' acquisition costs, thereby causing Medicare and Medicaid to "overpay" providers – were publicly disclosed long before the Florida II Complaint was filed on August 13, 1997 by a series of reports prepared by the U.S. Department of Health & Human Services, Office of the Inspector General ("HHS-OIG") and the United States General Accounting Office ("GAO"), news media, and Government audits and investigations. *See United States ex rel. Waris v. Staff Builders, Inc.*, No. 96-1969, 1999 U.S. Dist. LEXIS 15247, *11 (E.D. Pa. Oct. 4, 1999) (publicly available reports prepared by governmental agencies are "paradigmatic example[s]" of public disclosures under section 3730(e)(4)(A)); *United States ex rel. Alcohol Found., Inc. v. Kalmanovitz Charitable Found., Inc.*, 186 F. Supp. 2d 458, 463 (S.D.N.Y. 2002), *aff'd*, 53 F. App'x 153 (2d Cir. 2002) (articles in the "news media" constitute public disclosures); *Seal 1 v. Seal A*, 255 F.3d 1154, 1161 (9th Cir. 2001) (public disclosures through investigations). The disclosure need not actually identify the defendant, if it "'set the government squarely on the trail of fraud' such that it would not have been difficult for the government to identify…a potential wrongdoer." *West*, 538 F. Supp. 2d at 383 n.10 (quoting *United States ex rel. Fine v. Sandia Corp.*, 70 F3d 568, 571 (10th Cir. 1995).

A. The Core Allegations Were Disclosed in News Media and Government Reports

In June of 1996, more than a year before Ven-A-Care filed its first *qui tam* complaint against Dey, the HHS-OIG issued two reports discussing Medicare reimbursement payments from January 1994 to February 1995 for Albuterol UD. The first report, entitled "A Comparison of Albuterol Sulfate Prices" ("Pharmacy Report"), compares the prices Medicare pays based on AWPs to reimburse pharmacists for Albuterol UD to prices available to pharmacies that were members of pharmaceutical buying groups. *See* SJ Ex. 48. The Pharmacy Report finds that, while the Medicare allowance for Albuterol UD at the time was $0.43 per milliliter, members of the surveyed pharmacy groups could purchase Albuterol UD for prices ranging from $0.19 per milliliter to as low as $0.13 per milliliter. *See id.* at p. 5. The second report, entitled "Suppliers' Acquisition Costs for Albuterol Sulfate" (the "Suppliers' Report") compared Medicare's reimbursement payments based on AWPs to prices paid by suppliers for generic versions of Albuterol UD. *See* SJ Ex. 49. The report similarly found that, while Medicare paid providers between $0.40 and $0.43 per milliliter, suppliers paid, on average, $0.23 when they purchased from a pharmacy, $0.20 when they purchased from a wholesaler, and $0.14 when they purchased direct from a manufacturer. *See id.* at pp. 6-7. The Suppliers' Report also states that, during the time period which these reports examine (January 1994 to February 1995), Medicare reimbursement payments for a multi-source drug, such as Albuterol UD, were calculated based on the median of the AWPs for all the generic versions of that drug "using *The Red Book* or similar sources which list the average wholesale prices pharmaceutical companies self-report for their products." *See id*. at 2. The Government based both of these reports, in part, on invoices for Dey's drugs from 1994 to 1995. *See, e.g.*, SJ Ex. 57.

In November 1998, more than a year before Ven-A-Care made any allegation concerning

Ipratropium, the HHS-OIG issued a report entitled, "Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs" (the "VA Report"), which compares Medicare reimbursement payments for certain drugs, including Ipratropium, with prices available to the Department of Veterans Affairs (the "VA"). *See* SJ Ex. 51. The VA Report finds that the VA "can get prescription drugs for a drastically lower price than Medicare." *Id.* at 9. Specifically, the VA Report finds that, in 1998, the VA's price for Ipratropium was $1.31, while the Medicare allowance was $3.34. *Id.* at App. B. *See also* Ex. 7 (Government working file containing Federal Supply Schedule prices for Dey's drugs).

Moreover, like Albuterol UD and Ipratropium, the other Dey Subject Drugs are nebulizer drugs. In February 1996, the Government published a report regarding nebulizer drugs entitled, "Medicare Payments for Nebulizer Drugs." *See* SJ Ex. 47. In connection with this report, the Government obtained contract prices for Dey's drugs. *See, e.g.*, Ex. 8. In this report, the HHS-OIG found that Medicare could save money by discounting the AWPs used to reimburse all nebulizer drugs. *See* SJ Ex. 47 at pp. 9-10.

The "spreads" for Dey's drugs were also disclosed by First DataBank, Red Book and Medi-span. A simple comparison of Red Book's publications of AWPs and WACs for Dey's drugs reveals such "spreads," including mega-spreads for some of the drugs. For instance, in the first quarter of 1999, the AWPs reported by Red Book for Dey's albuterol sulfate metered dose inhaler and metered dose inhaler refill were $21.70 and $19.79, respectively. *See* Declaration of Lauren Stiroh in Support of Defendant Dey, Inc., Dey, L.P., and Dey L.P., Inc.'s Motion for Partial Summary Judgment, Docket No. 6182, at Figures D, H. The WACs published by Red Book for those products were $4.10 and $3.95 respectively, resulting in "spreads" of 429% and 401%. *See id.* At that same time, for Dey's albuterol sulfate multi-dose, Red Book reported an

AWP of $14.99 and WAC of $5.05, resulting in a "spread" of 196%. *See id.* at Figure I.

That published prices exceed actual acquisition costs has been well documented in numerous other reports prepared by the federal government, in particular by the HHS-OIG and the GAO, for years before Ven-A-Care filed its action, including the following:

- In 1968, the United States Secretary of Health, Education, and Welfare's Task Force on Prescription Drugs found: "*Red Book* and *Blue Book* do not reflect the actual manufacturer' prices to wholesalers and retailers, which are determined by the amounts of various kinds of discounts." *See* Ex. 9 at p. 31.

- In 1984, the HHS-OIG reported that "AWP represents a list price and does not reflect several types of discounts, such as prompt payment discounts, total order discounts, . . . rebates, or free goods that do not appear on the pharmacist's invoices." *See* Ex. 10 at pp. 3, 6.

- In 1989, the HHS-OIG reported: "[w]e continue to believe that AWP is not a reliable price to be used as a basis for making reimbursements for either the Medicaid or Medicare Programs." *See* Ex. 11 at p. 7.

- In 1994, in a report comparing prices for pharmaceuticals in the United States to prices in the United Kingdom, the GAO noted: "Some observers have criticized the use of WAC as a measure of manufacturers' prices because it does not capture manufacturers' discounts and prices to certain customers. However, the WAC is the correct measure for an analysis of the undiscounted segment of the U.S. pharmaceutical market." *See* Ex. 12 at p. 19, n.16.

- Between 1994 and 1995, the HHS-OIG conducted surveys comparing providers' acquisition costs to published AWPs. In 1997, the HHS-OIG issued two reports detailing the findings of its surveys on a nation-wide basis, one report for brand name drugs and one for generic drugs. In the report concerning generic drugs, the HHS-OIG found that providers' actual acquisition costs for the 200 generic drugs with the highest Medicaid reimbursement in 1994 and 1995 were, on average, 42.5% less than the AWPs reported in pricing publications. *See* Ex. 30 at p. 4. In Relator's parlance, this constitutes an average spread of 73.9%.[4]

- In a report issued in 1997, the HHS-OIG, found differences between Medicare reimbursement payments and providers' acquisition costs of up to 900%. *See* SJ Ex. 50 at p. 8.

This Court has previously held that these government reports contributed to an ever-

[4] Between 1996 and 1997, the HHS-OIG also published 11 reports detailing the findings of its survey as to the following states: California, Montana, Florida, North Carolina, Delaware, Virginia, New Jersey, Nebraska, Missouri, the District of Columbia, and Maryland. The findings concerning a comparison of AWP and providers' acquisition costs for generic drugs are consistent with the nation-wide findings of the 1997 Report. *See* Exhs. 13-23.

growing body of public knowledge of significant spreads between published prices for drugs and the actual average of acquisition costs to providers that, by August of 1997, constituted a sufficient notice to a private third-party payor such as Blue Cross Blue Shield of Massachusetts of the existence of a claim to start the running of the statute of limitations. *See In re Pharm. Indus. AWP Litig.*, 491 F. Supp. 2d 20, 79 (D. Mass. 2007).

The core allegations in the U.S. Complaint have also been disclosed in the news media. On July 5, 1987, more than 10 years before Ven-A-Care filed its first complaint against Dey, the Kentucky-based *Lexington Herald-Leader* published a front-page story entitled "Drug Industry Overcharging Medicaid Prescriptions Cost Taxpayers Millions of Extra Dollars." *See* Ex. 24 at p. 1. The article describes how Medicaid was making "overpayments," AWP is used to calculate reimbursements, and that the figures in Red Book, Blue Book, and Medispan are "in most cases . . . provided to the publications by the drug companies." *Id.* at 2, 3. The article also discusses in detail a "sales technique called 'playing the spread,'" stating that a large "spread, or difference, between the [AWP] and the actual price" meant that "a pharmacist buying that drug could make a larger profit." *Id.* at 4-5. The article further stated that some "companies actually advertised that they had a better spread" and that "many companies routinely list Average Wholesale Prices and 'your price' in their catalogs to show the spread." *Id.* at 5.

On June 10, 1996, more than a year before Ven-A-Care filed its first complaint against Dey, an article appeared in *Barron's* entitled, "Hooked on Drugs." *See* Ex. 25. The article's premise is almost identical to the allegations that would later be in the Florida II Complaint. The article states that: (a) Medicare and state Medicaid programs "generally use AWP as a benchmark for reimbursement" (*id.* at 3); (b) AWPs "originate with the manufacturer" and "for generic drugs, nearly every manufacturer's price was 60-85% below the published [AWP]" (*id.*

at 2-3); (c) "drug salespeople . . . let[] the doctor know that his product has a bigger spread between AWP and the real price than any other generic firm." (*Id.* at 3); (d) "[i]f manufacturers deliberately maintain lofty AWPs on their generic drugs . . . the drug makers might then gain market share and higher sales from their customers' over-utilization" (*id.*); and (e) "[s]ome of these AWP's actually have risen, while real wholesale prices have plummeted" *Id.* at 5.[5]

That none of these reports or articles mentions Dey specifically by name is irrelevant. "Industry-wide public disclosures bar *qui tam* actions against any defendant who is directly identifiable from the public disclosures." *United States ex rel. Gear v. Emergency Med. Assoc., Inc.*, 436 F.3d 726, 729 (7th Cir. 2006) (dismissing the case under 3730(e)(4) even though specific defendants in lawsuit were not identified in public disclosures); *see also United States ex rel. Findley v. FPC-Boron Employees' Club*, 105 F.3d 675, 687 (D.C. Cir. 1997) (finding a public disclosure where the defendants were "easily identifiable" based on the publicly disclosed information). Indeed, this Court itself has held that the jurisdictional bar can apply even though the public disclosure does not specifically identify the defendant, especially when it is not difficult from the public disclosure to identify that defendant. *West*, 538 F. Supp. 2d at 383 n.10.

Dey is readily identifiable from the publicly disclosed information. For example, at the time of the 1996 Albuterol UD reports, Dey was one of only ten generic manufacturers of Albuterol UD, according to the Blue Book. *See* Ex. 30. Likewise, at the time of the VA Report in 1998, Dey was one of three generic manufacturers of Ipratropium 0.02%. *See* Ex. 31.

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[5] *See also, e.g.*, Ex. 26, Harold Cohen, "There's Nothing 'Average' About AWP," Drug Store News, June 11, 1990, at p. 75 ("AWP has become an exploited figure that is often picked out of thin air by pharmaceutical manufacturers who know that as long as third-party programs continue to use AWP as a base for reimbursement, the higher the number the better their chances are of getting their product dispensed"); Ex. 27, "VA Obtains Rx Drug Price Discounts," The Pink Sheet, July 24, 1989, at pp. 5-7 ("For multiple-source products . . . the department 'typically' obtains 'discounts ranging from 39% to 93%, but most multiple-source drugs in our depots are currently being purchased with discounts of greater than 80%' off AWP."); Ex. 28, Harold Cohen, "AWPs Are a Joke, But No One Is Laughing," Drug Store News, May 1, 1989, at p. 195; Ex. 29, Barbara Demick, "When Drugstores Tell You No," Phila. Inquirer, Feb. 12, 1989, at G01.

Additionally, reports that do not explicitly mention the Subject Drugs constitute sufficient public disclosures because they describe industry-wide practices. *See, e.g.*, Ex. 10, at 3 ("*Within the pharmaceutical industry,* AWP means a non-discounted list price.") (emphasis added); Ex. 32, at 2 ("The objective of our review was to develop a nationwide estimate of the difference between actual acquisition cost of drugs by the retail pharmacy and AWP for generic drugs."); Ex. 12, at 19, n. 16 ("[T]he WAC is the correct measure for an analysis of the undiscounted segment of *the U.S. pharmaceutical market*.") (emphasis added).

These industry-wide disclosures were sufficient to "'set the government squarely on the trail of fraud' such that it would not have been difficult for the government to identify…a potential wrongdoer." *West*, 538 F. Supp. 2d at 383 n.10. Indeed, the Government had the ability to easily identify the spread on every drug eligible for reimbursement under Medicaid. Pursuant to 42 U.S.C. § 1396r-8 and the Medicaid Rebate Agreement, a drug is only eligible for Medicaid reimbursement if the drug manufacturer reports its Average Manufacturer Price ("AMP") for that drug to the Government. *See* SJ Ex. 34. AMP is defined as the "average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade" and "includes cash discounts allowed and all other price reductions…which reduce the actual price paid." The Government could have compared such "average…actual price paid" to published AWPs and WACs. Moreover, the Government had invoices for Dey's drugs, which could also be used for comparison purposes. *See* SJ Ex. 57.

B. The Core Allegations Were Disclosed to Ven-A-Care During the Government's Investigation of Dey

Ven-A-Care learned about Dey and Dey's drugs through industry-wide public disclosures in the form of a three year investigation by the OIG comparing published AWPs to prices paid by providers. As reported by *Drug Topics* in 1994, HCFA was "trying to develop an estimate of

the difference between the actual acquisition cost of RXs and the AWP" with "data . . . sought from 48 randomly selected chain and independent pharmacies in 12 randomly selected states." *See* Ex. 33. Among these randomly selected pharmacies was Cobo Pharmacy in Key West, Florida—a pharmacy owned and operated by Ven-A-Care's then-president Luis Cobo. *See* Ex. 34; Ex. 35, at 31:5-32:1; 103:22-106:4.

As part of the 1994 study, OIG agent Paul Chesser and his colleagues extracted the prices from these invoices to develop the percentage difference between AWP and providers' acquisition costs. *See* Ex. 36, at 464:8-469:16. Mr. Chesser was also the contact person for the pharmacies selected for the study, and he answered questions they had about the study. *See* Ex. 34; Ex. 36, at 616:1-13. Mr. Chesser testified that, when asked, he explained to pharmacies the purpose of OIG's study, which was not secret. *See* Ex. 36, 617:7-22.

The OIG began publishing the results of its study in 1996, more than a year before Ven-A-Care filed its first complaint against Dey. Ven-A-Care's officer T. Mark Jones, admitted that it knew of the OIG's study as early as 1994. *See* Ex. 37, at 417:21-418:18. Thus, the record shows that Ven-A-Care was made aware of an ongoing investigation about alleged AWP inflation by government investigators before it filed its first complaint against Dey in August 1997. This investigation constitutes a public disclosure as well. *See Seal 1*, 255 F.3d at 1161.

C. The "Marketing the Spread" Allegations Were Publicly Disclosed Before Ven-A-Care Alleged Them in a Complaint

Ven-A-Care did not allege in any of its *qui tam* complaints any specific instance that Dey "marketed the spread" for any of the Subject Drugs. Those allegations do not appear until the Government filed its Complaint in Intervention in 2006. In any event, the allegations that drug manufacturers marketed the spread were disclosed before Ven-A-Care filed the Florida II Complaint in, *inter alia*, the 1987 *Lexington Leader-Herald* article and 1996 *Barron's* article.

II. THE ALLEGATIONS IN VEN-A-CARE'S *QUI TAM* COMPLAINTS ARE "BASED UPON" THE PUBLIC DISCLOSURES

The allegations concerning Dey in Ven-A-Care's *qui tam* complaints are "based upon" the public disclosures because Ven-A-Care alleges makes the same core allegations, namely that providers' actual acquisition costs for the Subject Drugs are significantly lower than published prices. "[A] private citizen may not bring an action to enforce the False Claims Act where *similar* allegations have been publicly disclosed." *West*, 538 F. Supp. 2d at 379 (emphasis in the original). That a relator derives the allegations in its complaint from something other than the public disclosure is irrelevant. As this Court has previously held:

> An action is "based upon" a public disclosure when the supporting allegations are similar to or "the same as those that have been publicly disclosed . . . regardless of where the relator obtained his information."

United States ex rel. O'Keeffe v. Sverdup Corp., 131 F. Supp. 2d 87, 92 (D. Mass. 2001) (quoting *United States ex rel. Doe v. John Doe Corp.*, 960 F.2d 318, 324 (2d Cir. 1992).)

As set forth above, numerous HHS-OIG reports, GAO reports and published articles disclosed the industry wide practice of published prices reported by pharmaceutical manufacturers exceeding providers' acquisition costs. Ven-A-Care's allegations add nothing to what was already publicly known.

The allegations specific to Dey in the Florida II Complaint include little more than a comparison of wholesaler or GPO prices to AWPs for the Subject Drugs.[6] In the Dey-specific section of the Florida II Complaint, Ven-A-Care alleges that Dey caused AWP and DP to be published in Red Book and Blue Book that were much higher than the prices charged for those drugs in the marketplace, either by Dey or by wholesalers. *See* SJ Ex. 94 at ¶ 121. Ven-A-Care then provides charts which compare the AWPs for certain of Dey's drugs with Ven-A-Care's

[6] The amended complaints make substantially the same allegations regarding Dey as the Florida II Complaint and merely provide comparisons between published prices and GPO and wholesaler prices.

alleged acquisition cost. *See id*. For example, Ven-A-Care alleges that for Dey's Albuterol UD, the Red Book AWP is $30.25 and its cost is $8.50. These allegations merely reiterate what had been publicly disclosed before Ven-A-Care filed this complaint. Indeed, these allegations are almost identical to information contained in the Pharmacy Report and the Suppliers' Report, which were both published over a year earlier. For example, the Suppliers' Report found that suppliers' can purchase Albuterol UD for as little as $0.12 per milliliter, while the median AWP for generic versions was $0.43, resulting in a "spread" of 258%. *See* SJ Ex. 49 at p. 7. The spread between the Red Book AWP and the "Relator's Direct Cost" for Albuterol UD as alleged by Ven-A-Care is almost the same, at 255%. Moreover, the Suppliers' Report makes clear that the AWPs used by Medicare are set and reported by manufacturers. *See id*. at p. 2.

Ven-A-Care concedes – as it must – that the HHS-OIG published reports going back to 1980s reporting that AWPs exceeded AACs. *See* Ex. 46, at 799:12-803:5. Rather, Ven-A-Care claims that the magnitude of the spreads and the manufacturers' practice of "marketing the spread" had not been previously disclosed. *See id*. As to Dey, this claim is simply not true. As described above, the spreads for the Subject Drugs were disclosed before Ven-A-Care alleged them in its complaints by HHS-OIG reports and the publication of Dey's WACs as compared to AWPs. *See* SJ Exhs. 48, 49, 51. Additionally, a number of articles and reports allege the existence of so-called mega-spreads. *See* Exhs. 24-29. Moreover, Ven-A-Care never made any specific allegations of any act by Dey in which it "marketed the spread" for a Subject Drug.

III. VEN-A-CARE IS NOT AN "ORIGINAL SOURCE" BECAUSE IT DID NOT HAVE "DIRECT AND INDEPENDENT KNOWLEDGE" OF THE ALLEGATIONS CONCERNING DEY

Since the Complaint is based on publicly disclosed information, this Court lacks jurisdiction because Relator has not established that it is an "original source" of the allegations in the Complaint. Section 3730(e)(4)(B) defines an original source as follows:

> "[O]riginal source" means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

31 U.S.C. § 3730(e)(4)(B). To survive a subject matter jurisdiction challenge, Relator must prove its direct and independent knowledge on a "claim-by-claim" basis. *West*, 538 F. Supp. 2d at 379 (citing *Rockwell*, 127 S. Ct. at 1410). "A relator's knowledge is 'direct' if she acquired it through her own efforts without an intervening agency, and it is 'independent' if her knowledge is not dependent on the public disclosure." *West*, 538 F. Supp. 2d at 379 (quoting *O'Keeffe*, 131 F. Supp. 2d at 93). "[A]ny information supporting a FCA action that Relator gained through his analysis of existing data is [] insufficiently direct to make him an original source." *O'Keeffe*, 131 F. Supp. 2d at 96; *see also, e.g., United States ex rel. Kreindler v. United Techs. Corp.*, 985 F.2d 1148, 1159 (2d Cir. 1993) ("collateral research and investigations . . . [do] not establish 'direct and independent knowledge of the information on which the allegations are based within the meaning of § 3730(e)(4)(B)'"). "[T]o be independent, the relator's knowledge must not be derivative of the information of others, even if those others may qualify as original sources," *U.S. ex rel. Fine v. Advanced Scis.*, 99 F.3d 1000, 1007 (10th Cir. 1996), and must be independent of public disclosures. To prove its status as an original source, the relator may rely on only information that it voluntarily provided to the United States prior to filing its suit. *See In re Natural Gas Royalties Qui Tam Litigation*, 562 F.3d 1032, 1044 (10th Cir. 2009).

A. Ven-A-Care's Allegations Relating to Prices Are Based on Second-Hand Research Acquired From Third-Parties

There is no evidence that Ven-A-Care purchased a Dey drug prior to 2000 through which Ven-A-Care might have learned that Dey's published prices could have exceeded a provider's actual acquisition cost. *See* Ex. 38, at 1080:14-1082:19. Even in the year 2000 when Ven-A-Care purchased Dey's drugs, it only did so for purposes of these AWP litigations. *See id.*

Indeed, there is no evidence that Ven-A-Care ever dispensed a Dey Subject Drug to any Medicare or Medicaid patient, and accordingly, no evidence of any claim submitted by Ven-A-Care to Medicare or Medicaid for any Dey drug, *see id.*, let alone that such direct evidence was the basis of its allegations against Dey or that it provided such direct evidence to the Government before filing suit, as required by Section 3730(e)(4)(B). Nor was Ven-A-Care well-positioned to have obtained such evidence; by the mid-1990s, before Dey sold many of the Subject Drugs, Ven-A-Care had had largely stopped seeing patients, and its current president T. Mark Jones admitted that Ven-a-Care did not purchase every drug at issue in each of its lawsuits. *See* Ex. 37, at 382:19-383:8; Ex. 38, at 1276:12-1277:6.

Ven-A-Care's only so-called "direct knowledge" regarding Dey was derived from cost and price information from GPOs and wholesalers in the marketplace. *See* Ex. 46, at 786:11-788:13; *see also* Ex. 46, at 815:8-816-6, 873:19-874:4, 883:20-890:6, 893:11-895:12; SJ Exhs. 70-72. Ven-A-Care did not have a regular contact with Dey, but rather, like other GPO members, received the GPO contract prices from the GPO. *See* Ex. 46, at 868:19-869:6. These GPO prices were available to other GPO members with the same "membership criteria." See Ex. 46, at 846:20-849:16, 854:4-856:11, 870:1-5. Ven-A-Care's officer, Dr. John Lockwood, confirmed that "other pharmacies that were in the same class of trade as Ven-A-Care had the same pricing available in general that Ven-A-Care had," and that this "knowledge was not unique to Ven-A-Care but was probably known by every pharmacy that could buy these drugs, and/or did buy those drugs." Ex. 39, at 237:19-22; 243:15-22. The wholesaler prices provided by Ven-A-Care to the Federal Government were even more widely known than the GPO prices. As Ven-A-Care admits, anyone who owned a retail pharmacy could have contacted the wholesalers and obtained the same price sheets and catalogues. *See* Ex. 46, at 888:3-20.

Likewise, the wholesaler advertisements were sent to all of the wholesalers' customers. *See* Ex. 46, at 918:1-919:11, 924:11-927:16; SJ Exhs. 79, 80; Ex. 40. Therefore, since Ven-A-Care had no "firsthand knowledge" and the information was "derivative" of "others", which was widely disclosed, Ven-A-Care cannot be an "original source." *See O'Keeffe*, 131 F. Supp. 2d at 96; *Findley*, 105 F.3d at 690.

The comparisons of GPO prices and published prices alleged in Ven-A-Care's *qui tam* complaints do not convert Ven-A-Care's second-hand knowledge into "original source" knowledge. Indeed, this is essentially the same type of analysis the Government had been engaged in for years before Ven-A-Care filed its first *qui tam* complaint against Dey. For example, the Pharmacy Report, published in 1996, compared AWPs to prices available to pharmacies that were members of purchasing groups, or "GPOs". SJ Ex. 48 at pp. 2, 5. Since Ven-A-Care's comparison of the published prices and catalog prices for Dey's drugs is not "qualitatively different" from what the Government had already done in publicly disclosed reports, Ven-A-Care cannot be an original source. *See U.S. ex rel. Fried v. West Indep. School Dist.*, 527 F.3d 439, 443 (5th Cir. 2008) (holding that the relator was not an "original source" because the relator's allegations were merely the "product and out growth" of publicly disclosed information).

B. Ven-A-Care Based Its Allegations Against Dey on the Government's Investigation

Ven-A-Care's claims that it began communicating with the Federal Government regarding Dey's pricing for drugs "on or about August 25, 1995" are also not sufficient to establish that Ven-A-Care was the "original source." *See* Ex. 41, at p. 10. Ven-A-Care has not produced any evidence to support this claim. Ven-A-Care points to a one-page sales circular facsimile from Pulmodose, dated August 25, 1995, that Ven-A-Care forwarded to Mark Lavine

of the U.S. Department of Justice. *See* Ex. 42. However, the sales circular makes no reference to reimbursement under Medicare or Medicaid; it simply lists services and prices offered by Pulmodose for certain inhalation drugs. Moreover, when asked at a deposition, Ven-A-Care's 30(b)(6) witness could not confirm that the sales circular actually referred to Dey's drugs. *See* Ex. 46, at 828:4-8. Indeed, the list includes Ipratropium, a drug that Dey did not begin selling until 1997, and thus cannot possibly be Dey's drug.

The earliest piece of evidence sent from Ven-A-Care to the Federal Government, which Ven-A-Care has confirmed to concern Dey, is a facsimile, dated March 19, 1996, sent from Ven-A-Care to Robert Vito of the OIG, attaching Dey's AWP list and GPO contract prices for Dey's drugs. *See* Ex. 68. Ven-A-Care testified that it sent this facsimile pursuant to Robert Vito's request. *See* Ex. 46, at 860:14-863:1. According to Ven-A-Care, Mr. Vito requested this pricing information in connection with an OIG report – possibly relating to albuterol or the utilization of inhalant drugs. *See id*. However, Ven-A-Care admits that the OIG decided to prepare this report, not Ven-A-Care, and that it has no knowledge as to the sources actually used as the basis for the report. *See id*.; Ex. 46, at 863:8-864:6.

In any event, the OIG had learned of the so-called "reimbursement discrepancies" for Dey's drugs well before Ven-A-Care sent Dey prices to Mr. Vito in March of 1996, and even before Ven-A-Care sent the Pulmodose sales circular to Mark Lavine in August of 1995. The OIG had commenced the investigation that led to the Pharmacy Report and the Suppliers' Report in 1994. *See* Ex. 43, at 267:9-272:18. Moreover, in February of 1995, Mr. Vito received a facsimile from Dr. Robert Zone of CGLIC Medicare Administration, a Medicare DMERC, that contained an invoice from Dey for Dey's Albuterol UD and Cromolyn. *See* Ex. 44, at 1034:10-1040:14; Ex. 45. The invoice lists a price of $12.00 for Dey's Albuterol UD, or $0.16 per

milliliter. *See* Ex. 45. A list of Medicare allowable costs for nebulizer medications on the page directly preceding the invoice lists an allowable cost for Albuterol UD of $0.43 per milliliter. *See id.* Indeed, by November of 1995, through its own investigative efforts, the OIG had an extensive collection of pharmacies' invoices for Dey's Albuterol UD, showing prices ranging from $0.11 per milliliter to $0.16 per milliliter. *See* Ex. 44, at 1016:19-1032:19; SJ Ex. 57.

In short, it appears that Ven-A-Care based its allegations against Dey on the OIG's investigation. Therefore, Ven-A-Care cannot be an original source as to the allegations against Dey. *See Seal 1*, 255 F.3d at 1163.

For example, in *Seal 1*, the relator provided information to the Government about allegedly fraudulent activity committed by one company that prompted the Government to launch an investigation which uncovered fraudulent activity by another, unrelated company. *Id.* at 1156. The relator had no independent knowledge of fraud by the second company and only learned of it when he reviewed documents the Government had acquired during its investigation and spoke to Government attorneys about the investigation. *Id.* The court upheld dismissal of the relator's *qui tam* complaint against the second company on the grounds that the information relating to the second company had been publicly disclosed, at least to the relator, as a result of the Government's investigation into the second company, and that the connection between the information originally provided by the relator and the allegations that later formed the basis for the relator's complaint were too attenuated for the relator to be an "original source" as to the second company. *Id.* at 1163. Similarly, even if Ven-A-Care was the initial source to the Government regarding "reimbursement discrepancies" as to some drug products manufactured by another company, which Dey does not concede, those disclosures were not sufficient to establish that Ven-A-Care was the original source of its allegations against Dey and as to Dey's

Subject Drugs. *See Seal 1*, 255 F.3d at 1163.

C. Ven-A-Care Does Not Have Direct and Independent Knowledge of "Marketing the Spread" Allegations Against Dey

There is simply no evidence in the record or allegation in any Ven-A-Care complaint that Ven-A-Care had any knowledge, acquired independent of litigation initiated by the Government, of any act committed by Dey in which it "marketed the spread" for a Subject Drug. Moreover, since this practice was disclosed on an industry wide basis in 1987 in the *Lexington Herald-Leader* article and again in 1996 in the *Barron's* article, there is no jurisdiction over any claim by Ven-A-Care that Dey actively marketed the spread for its drugs.

D. Ven-A-Care Cannot Qualify as an "Original Source"

In addition to the foregoing, Ven-A-Care cannot be an "original source" of any allegations against Dey because Ven-A-Care is a company, not an "individual," and the FCA only permits an individuals to qualify as an "original source." *See* 31 U.S.C. § 3730(e)(4)(B). Indeed, while the FCA states that a "person" may bring an action under the FCA, the FCA explicitly defines "original source" as "an individual who has direct and independent knowledge." Id.; 31 U.S.C. §§ 3730(b)-(d). A company, like Ven-A-Care, may be a "person", but it is not an "individual." *See In re Spookyworld, Inc.*, 346 F.3d 1, 7 (1st Cir. 2003).

CONCLUSION

For the foregoing reasons, Dey respectfully requests that the Court dismiss Ven-A-Care's complaints, with prejudice, as to Dey, and grant Dey such other, further, and different relief as the Court deems to be just and proper.

Dated: June 29, 2009

Respectfully Submitted,

/s/ Sarah L. Reid

Paul F. Doyle (BBO # 133460)
Sarah L. Reid (*pro hac vice*)
William A. Escobar (*pro hac vice*)
Neil Merkl (*pro hac vice*)
KELLEY DRYE & WARREN LLP
101 Park Avenue
New York, New York 10178
Telephone: (212) 808-7800
Facsimile: (212) 808-7897

Attorneys for Defendants
Dey, Inc., Dey L.P., Inc. and Dey, L.P.

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on June 29, 2009, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Sarah L. Reid
Sarah L. Reid